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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,669	08/27/2001	Jens Petersen	60117.000004	2508

7590

05/17/2006

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1900 K Street, N.W.  
Washington, DC 20006

EXAMINER
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AZPURU, CARLOS A

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 05/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/938,669	<b>Applicant(s)</b> PETERSEN, JENS	
	<b>Examiner</b> Carlos A. Azpuru	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 27-33,35-42 and 44-71 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27-33,35-42 and 44-71 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. <u>05122006</u> |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                                  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12052005 &amp; 03102006</u> | 6) <input type="checkbox"/> Other: _____   |

### **DETAILED ACTION**

Receipt is acknowledged of the amendments filed 01/09/2006 and 03/10/2006.

Information disclosure statements were filed on 12/01/2005 and 03/10/2006.

The rejections under 35 USC 102(b) over RU'129, EP'232, and GB'578 are hereby withdrawn.

A telephone call was made to Mr Aksman in an attempt to correct the deficiencies cited below, but applicant did not agree to inserting language from the specification referring to the formula of the polymer and deleting reference to the backbone which is not discussed in the specification.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27-33, 35-42, 44-71 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 27 and 52 refer to a polyacrylamide which has a backbone consisting essentially of the formula  $(C_3H_5NO)_x$ . However, at page 9, lines 24 and 25 as well as Figure 1, no discussion is made of the backbone. The term does not appear anywhere in the original specification. While applicant may feel this is understood. Read in its broadest interpretation, applicant is seeking to broaden the invention disclosed since the backbone may be attached to a different hydrocarbon chain. Applicant is therefore requested to use the empirical formula disclosed at page 9, lines 24-25 in place of the reference to the backbone.

Claims 45-47, 68-70 refer to elastic modulus values not found in the original specification. If support is found in the parent provisional application, the pertinent sections of that application may be inserted here along with a statement citing page and line where they were originally located, as well as a statement that new matter has been added. Correction is requested.

Claims 27-33, 35-42, 44-71 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a hydrogel as set out in claims 27 and 52 which comprise at least 95% by weight pyrogen-free water or saline solution, does not reasonably provide enablement for a hydrogel without this major constituent. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicant set the percentage of water and the type of water used in the hydrogel of the invention at page 7, lines 28-29. This is especially pertinent since applicant is attempting to avoid immune reactions found in prior art hydrogels. Correction is requested.

Claims 28 and 52 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a hydrogel with at least 0.5% by weight and less than 3.5% polyacrylamide, does not reasonably provide enablement for a hydrogel having all % of polyacrylamide above 3.5. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicant is attempting to broaden the invention by extending the weight percent of polyacrylamide past 3.5%. However, since water makes up at least 95%, applicant would still be limited to 5% at the highest. It is therefore requested that the instant claims be deleted.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 50 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 50 is indefinite in that it refers to a syringe as a prosthetic device. A syringe may be used to administer the hydrogel which becomes the prosthetic device or

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endoprosthesis, but it is not itself a prosthetic device (see page 8, lines 8-9). The syringe could not be the prosthetic device "consisting essentially "of the defined polyacrylamide hydrogel since any polymer used in the syringe would be excluded. As such, it is suggested the claim be cancelled.

***Allowable Subject Matter***

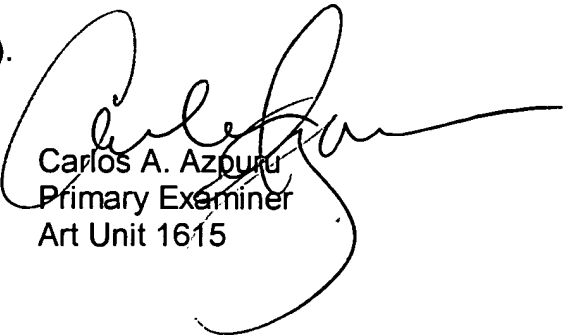
Correction as indicated above would place the application in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Carlos A. Azpuru  
Primary Examiner  
Art Unit 1615

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